Testimony before the

Subcommittee on Prevention of Nuclear and Biological Attack

Committee on Homeland Security

United States House of Representatives

Creating a Nation-wide Integrated Biosurveillance Network
May 11, 2006

Statement of

Richard E. Besser, M.D.
Director
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

Introduction

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am grateful for the opportunity to be here today to provide testimony on CDC's terrorism and emergency preparedness efforts, our efforts to enhance biosurveillance through continued implementation of the BioSense program, and the plans underway to enhance collaboration with the National BioSurveillance Integration Center at DHS. I am Richard Besser, Director of the Centers for Disease Control and Prevention's Coordinating Office for Terrorism Preparedness and Emergency Response. In this role, I have primary oversight and responsibility for all programs that comprise CDC's terrorism preparedness portfolio.

Overview of CDC's Preparedness Efforts

The health and security of the United States depends on our preparedness against terrorism, including bioterrorism, as well as other public health emergencies including the threat of pandemic influenza. These threats necessitate that we improve our public health and medical systems so that we can respond with greater flexibility, speed, and capacity to handle mass casualties and large-scale emergency response in coordination with our traditional emergency response partners as well as those at the Department of Homeland Security (DHS) and Department of Defense (DoD).

HHS is responsible for leading Federal public health efforts to ensure an integrated and focused national effort to anticipate and respond to emerging threats from biological and other weapons. HHS is also the principal Federal agency responsible for coordinating all Federal-level assets activated to support and augment the state and local medical and public health response to mass casualty events. Within HHS, CDC supports these activities through extensive coordination and collaboration with a number of federal departments and agencies. I will focus my remarks on CDC's role and accomplishments in terrorism preparedness and emergency response, with emphasis on the BioSense program.

CDC'S Strategic Preparedness Framework

CDC has made terrorism preparedness and emergency response a priority and has built an infrastructure to catalyze and implement biodefense activities and collaborate with our Federal, state, and local government partners as well as with the private sector, non-governmental organizations, and tribal nations. To do this effectively, CDC has established nine agency preparedness goals to strategically focus and efficiently direct CDC resources. These goals are aligned under three overarching categories: Pre-Event, Event, and Post-event. Taken together, these goals provide a strategic framework from which to establish and implement preparedness programs, with the goal of integrating our activities with those of our emergency response partners at all levels of government and the private sector. I would like to share with you some of the key activities CDC has undertaken and our progress toward achieving these goals, particularly in the arena of biosurveillance.

BioSurveillance for Enhanced Situational Awareness

Traditionally, public health surveillance systems were designed to identify trends in health indicators and identify diseases for reporting purposes. Historically, these were manual systems that evolved to computerized systems, but which remained fragmented and slow in exchanging information between clinical care providers and public health. CDC, through its new National Center for Public Health Informatics (NCPHI), has been pursuing fundamental changes in the way public health surveillance is conducted in the United States. NCPHI's efforts have been focused on upgrading information technology, standardizing data across multiple settings, and establishing systems for electronic data exchange. These changes are important to all of our public health efforts – but are particularly critical to our efforts in terrorism preparedness and response. In the event of a bioterrorism attack or widespread outbreak, traditional systems may fail to identify ill persons quickly enough for the delivery of appropriate countermeasures, increasing the likelihood of further transmission of disease or death. To achieve this level of information timeliness, biosurveillance systems must be electronic and enable transmission of existing health information to public health decision-makers in real-time. Such systems will not only assist public health to detect disease early and identify persons affected, but will also help to confirm or refute the presence of illness in a given community, characterize the progression of an outbreak once it's identified, and assess the effectiveness of control measures.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, required specific activities to improve the nation's preparedness for bioterrorism and other public health emergencies by increasing coordination and planning among federal, state, and local public health and healthcare providers. The Secretary of HHS was required to provide for the establishment of an integrated system or systems of public health alert communication and surveillance networks among (1) federal, state, and local public health officials; (2) public and private health-related laboratories, hospitals and other health care facilities; and (3) other entities that the Secretary determined appropriate. Coordination of these surveillance networks is intended to provide channels for secure and timely sharing and discussion of essential information concerning bioterrorism and other public health emergencies as well as recommended methods for responding to such an attack or emergency.

The 2002 Act clearly highlighted the need for improving public health's capabilities for electronic health surveillance. HHS outlined two strategies aimed at achieving this goal: (1) unifying public health surveillance architectures to allow for the exchange of information among health care organizations, organizations with which they contract, and state and federal agencies and (2) streamlining quality and health status monitoring to allow for a more complete look at quality and other issues in real-time and at the point of care.

BioSense is the response to the Public Health Information Technology Initiative set forth by HHS. BioSense is a national program intended to improve the nation's capabilities for conducting near real-time biosurveillance and health situational awareness through access to existing data from healthcare organizations across the country. The visible component of BioSense is the web-based application which enables healthcare facilities and state and local public health organizations to see data from their own communities.

_____

Nation-wide Biosurveillance Network
House Homeland Security Subcommittee   May 11, 2006
On Prevention on Nuclear and Biological Attack   Page 2

Overview and Objectives of the BioSense Program

Currently, the majority of health-related information systems that exist nationally vary in their ability to share data to support immediate biosurveillance needs. Many local public health agencies lack the resources, the desire, and/or the needed expertise to develop and support a local comprehensive biosurveillance system. Therefore, CDC is developing a single national system that allows local use of local health data. There is no other system that conducts real-time electronic biosurveillance on a national scale. BioSense will connect existing health information to public health in a way not previously possible, by providing public health access to data from hospitals, healthcare systems, and other sources. BioSense is developing and implementing enhanced capabilities to rapidly detect and monitor bioterrorism, natural disease outbreaks, and other events of public health importance. In addition to early event detection, BioSense will support on-going investigations and responses of suspected bioterrorism or outbreak events by providing real-time health situational awareness. The primary objective is to expedite event recognition and response coordination among federal, state, and local public health and healthcare organizations by providing each level of public health access to the same data, at the same time.

Specifically, BioSense focuses on:
♦ Data transmission – to assure the secure, timely, routine receipt of health data for public health surveillance;
♦ Data analysis – utilize advanced analytic methods to detect events and to enable cities and states to use these methods to interpret results in as close to real-time as possible;
♦ Data reporting – on a near real-time basis, provide useful views of the data, including time series analysis and geospatial displays, for colleagues in state and local health departments, as well as for CDC program staff;
♦ Public Health Response – to provide local data to state and local public health officials, and support their use and interpretation of these data for investigations, outbreak response and public health interventions.

Community preparedness is at the foundation of BioSense. State and local public health authorities are one of the real "end users" of BioSense, because they are the first responders to health events. State and local public health authority to investigate and mange outbreaks will not be superseded by CDC. Traditional protocols for public health investigations at the local level will continue be the standard and CDC will only assist public health departments when invited. In alignment with CDC's community health protection goal "People prepared for emerging health threats," BioSense contributes to community preparedness by enabling public health activities related to achieving four specific preparedness goals:

CDC Preparedness Goal #2 – Decrease the time needed to classify health events as terrorism or naturally occurring, in partnership with other agencies.
▪ BioSense will provide, on a near real-time basis, standardized health data with broad geographical coverage to local, state, and federal public health jurisdictions. Currently, public health must rely on an amalgam of electronic and manual processes in a waterfall

model of reporting (hospital to local to state to CDC) making the event identification process fraught with underreporting and delay.
- Providing this "window on the status of community health" will reduce the amount of time it currently takes to access data needed to classify naturally occurring outbreaks and potential bioterrorism events.
- BioSense will also employ natural language processing and statistical and science-based algorithms that help recognize potential outbreaks and provide access to supporting clinical data about the cause of the outbreak.

CDC Preparedness Goal # 4 – Improve the timeliness and accuracy of communications regarding threats to the public's health.
- BioSense allows for simultaneous access of the same data by all levels of public health and the healthcare systems that are contributing data. If any one level identifies a suspected event, others (including the healthcare organization itself) can be invited into a coordinated conversation based on current, detailed healthcare data. This allows better communication regarding necessary action, further investigation, or mobilization of resources.
- BioSense provides cross-jurisdictional views that can help identify events that may be occurring simultaneously in multiple and/or neighboring jurisdictions. This is not possible with local surveillance systems limited by political, geographical, and jurisdictional boundaries.

CDC Preparedness Goal # 5 – Decrease the time to identify causes, risk factors, and appropriate interventions for those affected by threats to the public's health.
- BioSense will employ technological and data standards to connect public health to a breadth of real-time healthcare data not currently available to state and local health agencies and CDC. The focus will be on accessing existing health data from emergency departments, hospitals, clinics, and other related data sources in the major U.S. metropolitan areas. Timely access to the breadth of health data described below will give public health the tools to identify probable disease causes more quickly and make more informed intervention choices.
- BioSense includes the following data types:
  - Foundational (demographics, chief complaint, presumptive or working diagnosis, disposition, hospital utilization)
  - Clinical (vital signs, triage notes, discharge summary and diagnosis)
  - Laboratory (laboratory orders, microbiology results)
  - Pharmacy (medication orders)
  - Radiology (Radiology orders, radiology interpretation results)
- Having access to a centralized and standardized data set will also provide the ability to perform retrospective analyses across multiple jurisdictions and data types. Information from these analyses can then be applied to future events to identify causes earlier and begin interventions more quickly.

Preparedness Goal # 6 – Decrease the time needed to provide countermeasures and health guidance to those affected by threats to the public's health.

▪ Using BioSense, public health can understand the number of patients presenting at healthcare organizations, what their symptoms are, and what actions clinicians are taking to diagnose and treat. This allows public health to determine what information is needed by clinicians to guide care decisions, and to properly inform the general public regarding actual versus perceived health risks.

▪ In addition, understanding of available hospital resources, as available in BioSense, allows effective and timely countermeasures and guidance to early responders and officials.

Current Status and Goals of the BioSense Program

After the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 was enacted, BioSense was developed and began receiving data from Veterans Affairs and the Department of Defense ambulatory care clinics as well as laboratory test orders from LabCorp – the largest commercial laboratory in the United States. In 2005, CDC received additional funding to expand BioSense to receive real-time clinical data from public and private hospitals and healthcare facilities. Beginning with hospitals in 10 large metropolitan areas, CDC is developing a real-time clinical information surveillance system that, when fully deployed, will be a rich and timely data warehouse for early event detection and situational awareness. It will require substantial funding, take several years to develop and refine, and require input from the users and other stakeholders, but the potential benefit of this program to public health is tremendous. As national efforts focus on advancing the clinical health information technology component --- crucial for the care of each individual patient --- it is equally crucial that the overall public health system surveillance component is built to allow for efficient public health response based on accurate and timely information.

BioSense receives, analyzes, and evaluates health data from numerous data sources such as emergency rooms, ambulatory care clinics, pharmacies, poison control centers, and clinical laboratories. In addition to data from VA and DoD treatment facilities, and LabCorp, BioSense also receives data from over 30 health care facilities in 10 major metropolitan areas in the U.S. In 2006, CDC's goal is to begin receiving real-time data from up to 40 metropolitan areas, including a total of up to 350 healthcare facilities. In April, 2006, CDC released a new version of the BioSense application which includes health situational awareness functionality and access to the new real-time data streams.

Evaluation

CDC recognizes the need to perform evaluations of BioSense as it is developing. BioSense recently underwent a formal review under HHS' ongoing program to review major IT investments, and the findings were favorable. CDC is working with the Gartner Group, a major independent IT consulting firm, to complete an assessment of the BioSense system to ensure the chosen architecture and implementation approach is in alignment with industry best practices. This assessment is expected to begin May, 2006 and be completed over a six month period. The intent of the study is to do a thorough review of all aspects of the BioSense technical

architecture, platform and operations. The study will identify strengths and weaknesses as well recommendations for improvements.

CDC also plans to award a cooperative agreement to scientifically evaluate a number of aspects of the BioSense system including usability, validity of data, and usefulness of data types. In addition, the National Center for Public Health Informatics at CDC will be engaging Centers of Excellence in Public Health Informatics to provide input and focus on the efforts of the Center, including BioSense. To complement these activities, CDC has also funded four grantees to develop the science of early event detection and situational awareness through the secondary use of existing information in electronic, health-related databases. The grants focus on three broad areas: 1) increasing the sensitivity and specificity of detection algorithms, 2) establishing the efficacy of different data sources, and 3) developing software methods and components compatible with the Public Health Information Preparedness Initiative functional and technical specifications.

In addition, CDC is seeking input and feedback on BioSense from the state/local public health and hospital users in the form of a Users Meeting scheduled for May 23-24, 2006 in Atlanta. The goal of the meeting is to gain vital input and open an ongoing communication channel with the user community. In addition, approximately 25 nationally recognized experts in informatics and biosurveillance are being invited to meet with CDC as a Science Group, planned for June 27, 2006. This group will focus on the science of the system including appropriate algorithms, analysis and visualization techniques, and data streams of interest.

Privacy
Privacy and confidentiality of health data is extremely important to CDC, and in addition to the security measures in place, we have taken several steps to ensure the protections of the data transmitted through BioSense. Most importantly, obvious patient identifiers are excluded from the data transmitted through BioSense. In addition, data sharing agreements are signed with each hospital that define the authorized CDC and public health uses and responsibilities regarding the data. BioSense records are protected by the medical records privacy regulation under the Health Insurance Portability and Accountability Act, and CDC takes even further steps to apply other legislative authorities to ensure these data are afforded maximum confidentiality protections.

Electronic Data Sharing Standards and
Information Sharing with the Department of Homeland Security
The work conducted in the National Center for Public Health Informatics, and in particular through BioSense will support the HHS Office of the National Coordinator for Health Information Technology (ONC) Health Information Technology Standards Panel (HITSP). HITSP is a collaborative effort to harmonize health information interoperability standards, particularly health vocabulary and messaging standards. Through HHS' ONC, BioSense also supports the work of the American Health Information Community (AHIC or "the Community") and specifically the BioSurveillance Workgroup. The Community was formed to help advance efforts to reach President Bush's call for most Americans to have electronic health records within ten years. Chaired by the Secretary of HHS, the Community provides input and recommendations to HHS on how to make health records digital and interoperable, and assure

the privacy and security of those records. The standards set forth by the HITSP collaboration will be presented to the Community for endorsement. BioSense data standards directly support the work needed to make the AHIC recommendations a reality.

In addition to the support of HHS and AHIC standards, The National Biosurveillance Initiative, launched in 2005, directed Federal agencies to enhance biosurveillance capabilities to reduce the detection time following an attack, confirm the size and characteristics of the attack, and initiate a response. The initiative establishes a National Biosurveillance Integration System (NBIS) at the Department of Homeland Security (DHS) to combine and analyze information collected from human, animal and plant health, food and environmental monitoring systems. Such an analysis, combined with evolving threat and intelligence information, will provide greater context for those making critical homeland defense decisions. This is a broader system which BioSense summary data will complement.

CDC has engaged in initial discussions with DHS staff to determine those data that would be most useful for sharing as part of the NBIS data integration efforts. Specific data types will be determined over the coming months as the information available through BioSense and other biosurveillance systems are evaluated for their validity and usefulness. CDC welcomes further guidance and ongoing discussions with DHS to advance the sharing of critical public health information to enhance homeland security efforts.

Thank you for the opportunity to share this information with you. I am happy to answer any questions.

_____

Nation-wide Biosurveillance Network
House Homeland Security Subcommittee   May 11, 2006
On Prevention on Nuclear and Biological Attack   Page 7